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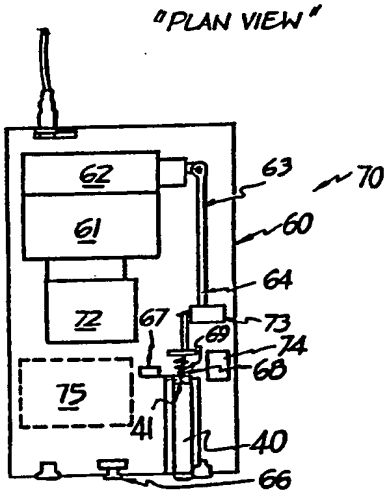
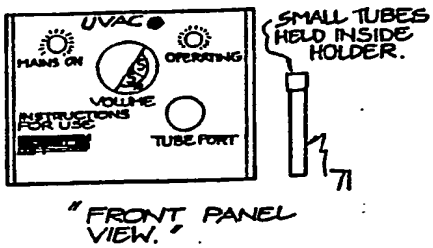
(54) Title: COLLECTION TUBE WITH PRE-COLLECTION EVACUATOR

(57) Abstract

A closed fluid sample collection tube evacuating apparatus (70) is disclosed for evacuation of a closed fluid sample collection tube (40) just prior to collection of a fluid sample of predetermined volume in relation to the volume of the sample tube (40), the apparatus (70) comprising: evacuation means (62, 61) mounted in or on a housing (60), and adapted to evacuate a closed sample tube (40) to a required vacuum being derived from a predetermined degree of vacuum or to one of a series of predetermined degrees of vacuum, and communication means (68) for connection of the evacuating means (61, 62) to the sample collection tube (40) to enable evacuation of said tube (40) to the required vacuum. The specification also discloses various methods of evacuating a tube (40), inter-tube transfer of fluid and a system for collecting a fluid sample. A method of collection of a biological fluid sample, particularly a blood sample is also disclosed.





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Collection Tube with pre-collection evacuator

Technical Field

The present invention relates to an apparatus and method(s) for drawing fluid using evacuation of an enclosed space or a chamber. Particularly, the present invention may be used or adapted for use in the medical field or environment, although the present invention may equally be adapted to many other fields (such as veterinary or chemical) where evacuation is required.

In a more specific form, the present invention deals with an apparatus and method for collecting, transferring and/or handling of body fluid or any other suitable fluid.

Background Art

Herebefore, syringes have commonly been used for the collection of blood or other body fluid samples. A syringe needle can be used to pierce a blood filled vein or other organ from which body fluids are to be sampled. The syringe plunger can then be retracted, such that, a vacuum is created in the syringe body. Blood flows or is drawn into the syringe body by this vacuum. Once a prescribed or desired sample has been taken, the syringe can be withdrawn from the vein. In order for analysis to be carried out on the blood sample taken, the sample must first be transferred into another more suitable vessel. This transfer involves exposing the sample, such that spillage or contamination of the sample, the people handling the sample and the working environment may occur. Most often, the blood sample is transferred to more than one other vessel, each transfer accentuating the possibility of spillage or contamination of the sample.

Pre-evacuated tubes have also been herebefore used. The tubes commonly used have been made only of glass, since plastic tubes do not reliably retain a vacuum for an extended period of time. These pre-evacuated tubes are expensive and also have a preset vacuum therein which is used to draw a measured or preset amount of blood sample. The present vacuum is susceptible to leakage due to the

glass containers imperfect sealing especially where there is an extended period between the time of the manufacture and sealing of the evacuated tube and the time of its intended use. Accordingly, amounts of fluid drawn by the pre-evacuated tubes can vary from tube to tube. Often, in use, a large blood sample is drawn, then smaller samples are obtained, via transfer and handling, with the dangers as described above.

In another method the sample is taken by means of a syringe body having an external needle fitted to the inlet thereof for insertion into a vein of a patient and internal needle projecting into the syringe body. In use, an evacuated glass sample tube sealed as described above is depressed into the syringe body. The internal needle pierces the plug and on passing fully through the plug permits blood from the patient to be drawn into the sample tube by the vacuum therein. Withdrawal of the plunger/sample tube once full, results in withdrawal of the internal of the needle from the plug. The material of the plug is such that the orifice formed by the needle is effectively resealed when the needle is withdrawn. As indicated, the same tubes are evacuated and must be of glass as synthetic plastics materials cannot hold the required vacuum for the necessary shelf life of the sample tube, which until now had not been able to be evacuated, in situ. An alternative tube comprises a glass tubular body having a screw threaded open end and an appropriate screw cap with an orifice in the end or top thereof. The tube is sealed by way of an appropriate rubber (or other material) disc inserted between the tube and the cap which provides the plug through which the needle is passed. These sample tubes are normally evacuated or subject to a certain reduced pressure to withdraw a set volume (e.g. 5 ml), 10 ml) blood sample.

These known sampling methods and apparatus suffer from various disadvantages. For example, as the sample tube must be glass it is liable to break if accidentally dropped or mishandled. Such breakage can be dangerous when the tube is evacuated due to the result of implosion. Such breakages

can expose personnel using the methods and apparatus to unnecessary risks where blood samples being taken may include virulent or infectious bacteria or viruses such as the variant HTLV-IV viruses.

As noted above, the sample tubes may be used at some long and indefinite time after manufacture and evacuation, the degree of evacuation of the tube may be uncertain and thus a blood sample, of insufficient volume for a particular test, may be withdrawn from a patient. Thus additional samples must be taken from the patient, resulting in a waste of time and materials and perhaps removal of too much blood from a patient.

Other apparatus have also been contemplated. Australian Patent Application No. 62,185/69 published 22nd April, 1971 discloses a device for drawing fluid in a manner similar to a syringe. An outer barrel, closed at one end, has a stopper inserted therein. The barrel with the stopper is then fitted to a connector. As the barrel is fitted, the connector pushes the stopper to the bottom of the barrel. The stopper is then attached to the connector by jaws. The connector when used is in communication with a fluid reservoir. The fluid is drawn into the barrel by retracting the barrel from the connector causing fluid to be drawn into the void left by the stopper. When the barrel is full, it can be detached from the connector, whereupon the stopper is released by the connector and forms a plug for the barrel. This apparatus has the disadvantage of using the same connector (needle means) for piercing the vein of a patient for each sample taken. This increases the risk of disease transfer. If, the connector is only used once and dispensed, then the disclosed apparatus is very expensive to use. Furthermore, withdrawl of sample is preset in volume and dependent on the reliability of the stopper. Barrels containing anti-coagulant are not contemplated, since complete depressing of the stopper into the barrel upon fitting the barrel to the connector is not possible.

U.S. Patent Specification No. 3,965,889 granted 29th June, 1976, discloses a vein piercing device comprising

a double ended needle, one for piercing the vein and the other end for piercing a tube adapted to fit within the device, for communication of fluid from the vein to the tube. The tube has therein a sack which is expandable by means of a vacuum supplied by a pump to the tube. As the vacuum is applied to the tube, the sack expands, drawing fluid from the vein. This apparatus is high in cost, most cumbersome in use as a pump is not always readily available for use and, again, the same neeedle is used to pierce the vein for each sample, thereby increasing considerably the risk of contamination.

Australian Patent Specification 506,875, published 9th March, 1978, discloses a device for evacuating a tube just prior to taking a fluid sample from a vein. The device is adapted to receive a tube having a pierceable stopper therein. Upon insertion of the tube, the device pierces the stopper, thus providing communication between the tubes interior and a chamber within the device. As the tube is further inserted into the device, the tube causes a piston within the chamber to retract, thus causing a vacuum in the chamber and also in the tube. As the tube is still further inserted, the tube is disconnected from the chamber just prior to having the tube again pierced by a needle having its other end in a fluid reservoir or vein, thus allowing fluid to be drawn into the tube under vacuum. This device, however, suffers from several disadvantages, namely, the device is only adapted to receive one size of tube and can only draw a fluid sample of one size. The needle of the device can be re-used, thereby risking contamination of the sample or communicating disease. Furthermore, the device is difficult to operate. In use, the needle is inserted into a vein, and while the needle is situated in the vein, the evacuated tube is pushed onto the other end of the needle. As this pushing occurs, the needle in the vein can easily destroy or damage the vein while the device is moved about in order to pierce the tubes stopper. This can be very painful.

Definition of Terms

Reference to 'tube' throughout the specification should be read, unless otherwise specified, as including reference to a tube, a test tube, a resealable tube, closed tube, an enclosed space of any form or chamber. The 'tube' may be made of glass, plastic or any other suitable material. The type of material used is dependent upon the application.

Reference to 'fluid' throughout the specification must be read, unless otherwise specified, as including any liquid or gas, or combination thereof, or sample with which the apparatus and method of the present invention can be adapted or used. Preferably, body fluid or blood is contemplated by the term 'fluid'.

Disclosure of Invention

The present invention seeks to alleviate or overcome some or all of the disadvantages of the prior art by providing a method and apparatus for collecting fluid samples in which the sample is collected in a substantially synthetic plastics material tube which has been evacuated just prior to use.

The present invention provides, in one form, a closed fluid sample collection tube evacuating apparatus for evacuation of a closed fluid sample collection tube just prior to collection of a fluid sample of predetermined volume in relation to the volume of the sample tube, said apparatus comprising :

evacuation means mounted in or on a housing, said evacuation means being adapted to evacuate a closed sample tube to a required vacuum being derived from a predetermined degree of vacuum or to one of a series of predetermined degrees of vacuum, and

communication means for connection of said evacuation means to the sample collection tube to enable evacuation of said tube to the required vacuum.

A system for collecting a fluid sample comprising a tube adapted to receive and retain for a predetermined amount of time, a vacuum, the tube being pierceable or

needle penetrable so as to provide fluid communication between a fluid reservoir and the interior of said tube and for evacuating the tube, such that the sample drawn is of a predetermined volume in relation to the volume of the tube, just prior to collection of said sample,

said tube being adapted to substantially reseal after piercing so as to hold said vacuum for said time or to hold said sample,

evacuation means mounted in or on a housing and being adapted to evacuate the tube to a predetermined degree of vacuum or to one of a series of predetermined degrees of vacuum, and

communication means adapted to connect said evacuation means to said tube to enable evacuation of said tube to the predetermined degree of vacuum or to one of the series of predetermined degrees of vacuum.

A method of sampling a predetermined volume of fluid comprising the steps of :

providing a fluid path means in communication with a fluid reservoir,

selecting the predetermined volume of fluid required to be sampled from the reservoir,

selecting a resealable tube having an enclosed space adapted for evacuation and retaining a prescribed vacuum for a predetermined amount of time,

providing the tube with the vacuum by allowing the tube to be pierced such that communication is provided between a source of vacuum and the interior of the tube until the prescribed vacuum is instilled in the tube, and then disconnecting the tube from the vacuum source, whereby the tube reseals in order to retain the prescribed vacuum,

mating the tube with the fluid path means, piercing the evacuated tube and allowing the predetermined volume of fluid into the tube.

A method of collecting a fluid sample from a patient, comprising :

attaching a syringe body to a first hollow needle permanently or temporarily inserted in a vein of the

patient, said syringe body having a second internal hollow needle extending axially into the tubular internal cavity of the syringe body;

evacuating or partially evacuating a plastics material sample tube having a needle-penetrable stopper therein by piercing said stopper with a needle attached to a vacuum device, operating said vacuum device to evacuate or partially evacuate said sample tube, disengaging said evacuated or partially evacuated sample tube from said needle;

inserting the evacuated or partially evacuated sample tube into the internal cavity of the syringe body to cause the second internal hollow needle to pierce said stopper and enter said sample tube to allow the vacuum or partial vacuum to permit blood from the patient to flow into the sample tube; and

disconnecting said sample tube and said first needle, as desired, when desired volume or volumes of blood have been collected.

The syringe body may be connected to what is conventionally known as a "butterfly needle" which allows repeated access to the vein of a patient via a flexible tube and appropriate connector such as a Luer connector. Such arrangement permits the use of a clamp on the flexible tube to control the flow of blood into the evacuated sample tube. Too rapid a flow of blood, in young and elderly patients, can result in collapse of the vein.

A method of providing a resealable tube with a predetermined vacuum, including the steps of :

providing the resealable or needle penetrable tube having an enclosed space adapted for evacuation and retaining a prescribed vacuum for a predetermined amount of time,

mating the tube with communication means adapted to connect an evacuation means to said tube to enable evacuation of the tube to the vacuum, the evacuation means being mounted in or on a housing and being adapted to evacuate the tube to the vacuum,

allowing the tube to be evacuated by said evacuation means,

withdrawing the tube from the communication means whereby the tube reseals so as to hold the vacuum for the predetermined amount of time.

A method of inter-tube transfer of fluid, including the steps of :

providing a tube having the fluid therein,

connecting the fluid tube to a transfer means having a first portion adapted to receive said fluid tube and a second portion adapted to receive an evacuated tube, the first and second portions being fluid connected via a communication means providing a fluid path, the communication means being adapted to connect the interior of the fluid tube and the interior of the evacuated tube for said transfer of fluid,

providing said evacuated tube as described above,

ensuring the communication means is in contact with said fluid,

mating the evacuated tube with the communication means so that a fluid is transferred by means of vacuum.

Brief Description of Drawings

Preferred embodiments of the present invention will now be described with reference to the accompanying drawings, wherein :

Figure 1 shows one embodiment of the present invention in the form of a simple hand operated tube evacuator.

Figures 2 to 4 show in block diagram form various embodiments of the present invention.

Figures 5 and 6 show preferred embodiment realisations of Figures 2 and 3, respectively.

Figure 7 shows a device for use in inter-tube transfer of fluid.

Note, in the Figures and description, like numerals denote similar integers or devices.

Best Mode of Carrying Out Invention

Referring to Figure 1, the device 10 comprises a base 11 with front 12 and rear 13 brackets mounted thereon. The brackets 12 and 13 have mounted thereon cylinder 14 having piston 15 disposed therein and front 16 and rear 17 ends. Disposed in front end 16 is a socket member 18 having a bore therethrough and adapted to receive hollow needle 19 such that there is communication between the interior of the cylinder and the outside so that air or fluid may be drawn, by operation of the piston, through the needle into the cylinder.

The needle 19 may be releasably attached to the socket by standard tapered friction fit or a standard Luer fitting. Housing 20 is adapted to be releasably fitted via screw 21 to the front cover plate 12 to protect a user from accidental impalement on the needle 19. The socket 18 may include a ball or other valve means to permit passage of air only from needle 19 to cylinder 14. When the piston is operated (as will be later described), a vacuum can be generated by movement towards the right or rear of the device. The cylinder may also include non return valve 22 to permit easy expulsion of air from the cylinder 14 when the piston is operated towards the left or front of the device. The rear end 17 of the cylinder may include, as is customary, bleed hole 23. A cover 24 including rear plate 25 is provided to enclose the piston 15 and cylinder 14 and includes a slot 26 adapted to engage slide member 27 connected to an end member 28 of piston rod 29.

Slide member 27 is adapted to slide in slot 26 and is connected at pivot 30 to linkage 31. Linkage 31 extends and is pivotally connected at pivot 34 to handle 33 at a point between base pivot point 35 and hand grip 33a.

Operation of the handle 32 towards the left or front of the device causes piston 15 to move to the front of the cylinder 16 and force air from the cylinder 16 via valve 22. Operation of the handle 32 towards the right or rear of the device causes air to be drawn into the cylinder via needle 19 and socket 18. Thus, it will be seen that by

insertion of a sample tube 40, having a needle pierceable and resealable stopper 41, combination through orifice 38 over needle 19 and operating the handle 33a from extreme left to extreme right, will cause a partial vacuum to be formed in the sample tube 40 which is retained in the tube once it is removed from needle 19 due to the resilient nature of the material of stopper 41 which reseals once the needle has been withdrawn.

One advantage of the present invention is that the sample tube may be of synthetic plastics material in place of the presently used glass tube which is liable to shatter if dropped either prior to or after filling with the associated dangers. The synthetic plastics material tube, whilst not able to retain a partial vacuum indefinitely, retains sufficient vacuum for the intended purpose as it is partially evacuated just prior to use.

Any suitable synthetic plastics material may be used for the moulding of the tube provided that the material is chemically inert to the samples to be retained therein.

The material of construction of the evacuation device or pump 10 may be of any suitable metal or synthetic plastics material. It will be seen also that by appropriate callibration, variation of the stroke of the piston in the cylinder will produce a partial vacuum which will draw a blood sample of the desired volume (e.g. 5 ml or 10 ml or any other convenient volume) into the sample tube.

An alternative embodiment to that of Figure 1 can be realised by actuating the piston 15 by use of an electrical solenoid and spring mechanism (not shown) attached to rod 29, in place of the handle 31, level 31 and slide 27. The solenoid can be housed within cover 24 and arranged for axial operation so as to draw the piston to the right or rear when actuated, and, when released, the spring mechanism serves to return the piston to a base position to the left or front of the cylinder 14.

Furthermore, an ultra-violet light (uv) can be disposed about needle 19 so as to provide a radiation source which will substantially eliminate contamination occurring

between tubes to be evacuated when they are pierced by needle 19.

Referring now to Figures 2 to 4, there is shown in block diagram form various embodiments of the present invention. A pump 62 driven by motor 61 and mounted on a housing 60 is a primary source of vacuum. The pump 62 can be continuously operated or selectively or discontinuously operated. The pump 62 should provide, as an output, a vacuum greater than that required in the sample tube 40 for the drawing of the prescribed amount of fluid as a sample so as to overcome any losses in the device 70 and to ensure a rapid tube evacuation.

The pump 62 is connected to a manifold 65 which provides a means of selecting or adjusting the primary vacuum to the required vacuum. The required vacuum is an amount sufficient to draw the required or predetermined fluid sample into the evacuated tube. The volume of fluid drawn into the tube is dependent on the tube volume, for example, if the required vacuum draws, say, 5 ml into an 8 ml tube, then the same amount of vacuum will draw 10 ml into a 16 ml tube, and so on.

As shown in Figure 2, the manifold 65 can have a rotatory selector therein or attached thereto, for adjusting the primary vacuum input to the required vacuum output. The selector can be in the form of a 'loss' unit, involving a number of selectable holes which provide for a loss in vacuum. The larger the hole, the more vacuum lost. The manifold can be manufactured such that a number of holes can be incorporated into the manifold, each hole being of sufficient size to enable a required vacuum to enter a particular tube size. Other holes can correspond, respectively, to other tube sizes in order to draw a sufficiently sized fluid sample. The manifold can, alternatively, or additionally, incorporate a slideable hole selector or any other suitable means for obtaining from the manifold the required vacuum for each tube size, and/or, fluid sample size.

The manifold 65, preferably, includes a calibration means 59 and a measurement means 58. The calibration means 59 is used to stabilise and regulate the vacuum from the pump 62 to the manifold 65. The calibration means also sets a 'base line' vacuum, a vacuum from which, or relative to which, the required vacuum is determined. The calibration means 59, preferably, is in the form of a preset or calibrateable hole to set vacuum loss or a regulator of conventional form. The guage 58 or other gauges placed at suitable locations may be used as a means of ensuring correct vacuum(s) are maintained in or delivered by the device 70.

In order to minimise pump 62 'on' time, thereby extending the life of the pump and associated equipment, a tube sensor means 67 may be used to detect the presence or absence of a tube to be evacuated. The sensor 67 is preferably located adjacent the needle 68, such that, upon actuation of the sensor 67 by a tube, the pump 62 and manifold 65 attain the required vacuum just prior to the needle 68 piercing the tube stopper 41 and communicating with the interior space of the tube 40.

A motorised needle injector 73 to which the needle and its assembly are attached is also preferably used to move the needle into and out of communication with the tube's interior space. Upon actuation of the sensor 67, the required vacuum is attained as described above. Also, the sensor 67 can activate the needle injector 73 to move the needle toward the area where the tube is inserted or places in the device 70. The operator can hold the tube in place, and allow the injector 73 to push the needle 68 through stopper 41 and so allow the required vacuum to be applied to the interior space of the tube 40. After a few moments or at such time as the tube has been evacuated as required, the injector 73 can withdraw the needle from the tube and stopper. The stopper 41 is to be made of a resilient material so as to reseal the tube and substantially maintain the evacuation of the tube for a limited period of time. The injector 73 can withdraw or move the needle 68 to

such a position that, accidental insertion of an operator's finger into the device will not make contact with the needle. Also the sensor 67 can be made or placed such a way that it will not activate unless a tube of particular size or constitution is inserted into the device 70, in order to avoid accidental operator contact with the needle 68, for example, the sensor can be a photo electric cell set to detect an empty tube only and not activate if a finger, no tube or tube with serum or fluid is placed into the device 70.

An ultra-violet (uv) light 9 may also be disposed in the device 73 so as to radiate the needle in its resting or 'home' position. This will allow the needle to be substantially sterilised between tube insertions in order to minimise inter-tube contamination. Since the present invention evacuates sample empty tubes, inter-tube contamination is minimal since the device usually operates on 'clean' tubes and stoppers.

Figure 3 shows an alternative to the device described above, in that the manifold does not incorporate a vacuum selector. Rather, a pressure measurement sensor 78 monitors the vacuum being delivered to a tube inserted into the device 70, the measurement being fed to a control means 77. The control means 77 monitors the pressure measurement and when the required vacuum in the tube in the device is detected by sensor 78, the control means 77 can activate the value to close the vacuum to the tube. The control means 77 can also be used to switch on or off the pump after a predetermined amount of time so as to reduce wear on the parts of the device.

Figure 4 shows an alternative to Figure 3. A pressure sensor 79 can monitor the pressure (vacuum) delivered to a tube 40. The tube sensor 67 can activate the pump 62 and, when sufficient vacuum has been applied to the tube, the pressure sensor 79 can de-activate the pump 62, until the next tube is detected.

Figure 5 shows one preferred form of the present invention, generally denoted as device 70. Motor 61,

drives pump 62 which develops a primary vacuum. Tube 63 communicates this vacuum to manifold 65, which utilises a 'lossy' selector in order to provide the required vacuum to the tube 40. The 'lossy' selector utilises hole 64, or a series of holes, in order to reduce the primary vacuum to the required vacuum. As an example only, if the pump 62 delvelops - 87 KPa vacuum, calibrator 59 reduces this to about -68 KPa, then via the lossy connection 64,65, the connection means can induce -50 KPa into a 15 ml tube via needle 68. The evacuated tube can then draw 10 ml $\pm$ 0.25 ml of fluid or blood. Selection of the hole(s) is arranged via a rotatory selector switch 66. Switch 66 can also be arranged in a mechanism arm assembly so that the appropriate hole 64 can be selected via a slidable sleeve having a hole therein and being moved over a tube having holes therein so that alignment of holes occurs.

In this embodiment, the needle 68 is stationary and has a resilient means 69, preferably a spring disposed adjacent thereto. Tube 40 is inserted or pushed by an operator into device 70 via an access orifice, actuator switch or sensor 67 which activates motor 61 and pump 62 to produce vacuum. The seal or stopper of the tube is pierced by needle 68 while compressing resilient means 69.

The required vacuum is then installed in the tube. After a predetermined amount of time, preferably about 2 or 3 seconds, the operator can stop holding the tube in the device 70. The resilient means 69, effectively pushes the tube away from needle 68 and the operator can withdraw the tube for fluid sampling.

The needle assembly can alternatively or additionally be mounted on an injector assembly (73) as hereinbefore described.

Figure 6 shows another preferred form of the present invention wherein required or selected tube vacuum can be obtained by pump and/or motor control. In this example, a regulator 72 can be used to control the motor 61 which operates pump 62 such that a speed or time control affects the device 70 to provide the required vacuum to tube

40. A vent or bleed hole(s) 64 is or are optional, and may provide additional vacuum control. A reserve power supply means 75, 12V battery for example, may be provided to facilitate the device's portability. A selector 66 may be a 'pot' or other means for adjusting the extent of motor control by control means 72. A micro-processor can similarly be adapted to effect this type of device operation. An injector assembly 73 can be used to move the needle 68 to an injecting position (communication with a tubes interior) or to a home position (suitably placed to prevent accidental injury to operators or contamination). As an example, the injector 73 can comprise a motor having an arm mounted thereon in an off-set cam arrangement. Needle 68 can be attached to the end of the arm. The needle end of the arm can be slidably nestled in a guide means to ensure the needle is correctly positioned for insertion into a tube. The motor can be arranged in a 'one-shot' type operation, such that only one revolution per tube detection is performed.

An ultra-violet light 74 can also be disposed about needle 68 to reduce contamination between tubes. The uv light serves to substantially sterilise the needle.

A tube holder 71 may be provided to assist operators. If a tube is small in size, it may be placed in the tube holder such that handling of the tube is made less difficult. The tube holder may be adapted to position the small tube such that communication with the needle 68 is possible when the tube holder is placed in the device 70.

Referring now to Figure 7, once the sample tube 40 has been (partially evacuated), insertion of the tube (plug first) into a body 51, connected by exterior needle 52 or "bufferfly needle" to a vein of a patient (not shown), inner needle 53 can pierce the stopper 41 and provide fluid access to the tube thus allowing fluid to be drawn into the tube by way of the partial evacuation. It will be seen that by repeated application of more sample tubes, a series of fluid samples will be obtained without removing the needle 52 from the vein. It will also be appreciated that the sample tubes

may contain chemicals for initial reaction with a fluid sample as is known. This method can also be used for inter-tube transfer whereby, the needle 52 is inserted into a tube having a fluid reservoir therein. An evacuated tube 40 can be then placed about needle 53, so that the evacuation draws a fluid sample from the reservoir. For large samples, needle 52 may also include another tube of suitable size which can act as a 'breather tube'. This will allow a larger sample to be drawn into the evacuated tube.

A method of obtaining a predetermined volume of blood may include the steps of :

i) providing a communicating means with a blood reservoir;

ii) selecting the predetermined volume of blood required to be drawn from the reservoir;

iii) selecting a suitable tube;

iv) providing the tube with an appropriate vacuum to affect drawing of the predetermined volume of blood using the apparatus of the invention; and

v) mating the tube and communicating means such that blood is drawn from the reservoir.

Conventional variations and adaptations known to those skilled in the art are herein contemplated within the scope of the present invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A closed fluid sample collection tube evacuating apparatus for evacuation of a closed fluid sample collection tube just prior to collection of a fluid sample of predetermined volume in relation to the volume of the sample tube, said apparatus comprising :

evacuation means mounted in or on a housing, said evacuation means being adapted to evacuate a closed sample tube to a required vacuum being derived from a predetermined degree of vacuum or to one of a series of predetermined degrees of vacuum, and

communication means for connection of said evacuation means to the sample collection tube to enable evacuation of said tube to the required vacuum.

2. An apparatus as claimed in Claim 1, further comprising :

manifold means coupled between said evacuation means and said communication means, and being adapted to selectively determine each predetermined degree of vacuum.

3. An apparatus as claimed in Claim 2, wherein said manifold means comprises a selector means having a first portion from which the required vacuum is delivered and a second portion connected to said evacuation means, the second portion having at least one orifice of at least one size, each orifice corresponding to each predetermined degree of vacuum, and further wherein said selector means is adapted to select an orifice such that the corresponding predetermined degree of vacuum is reduced to the required vacuum.

4. An apparatus as claimed in Claim 2, further comprising calibration means coupled to said evacuation means for determining a base line vacuum.

5. An apparatus as claimed in Claim 4, wherein each predetermined degree of vacuum is determined from said base line vacuum.

6. An apparatus as claimed in Claim 4, wherein said calibration means comprises an adjustable vent, being adapted to adjustably reduce vacuum from said evacuation means.

7. An apparatus as claimed in Claim 1, further comprising guage means for providing an indication of vacuum.

8. An apparatus as claimed in Claim 1, wherein said communication means comprises needle means for piercing the tube and enable evacuation of the tube.

9. An apparatus as claimed in Claim 1, further comprising tube sensor means to detect the presence of a suitable tube for evacuation.

10. An apparatus as claimed in Claim 8, wherein said communication means further comprises injector means for moving said needle into communication with said tube for evacuation and to a rest position.

11. An apparatus as claimed in Claim 9, wherein said injector means comprises a motor adapted for one-shot operation and being coupled to an arm mount on an offset cam, the arm being coupled to the needle means, said injector means, upon actuation, moving said needle into a piercing position and into communication with said tube for evacuation and returning to the rest position.

12. An apparatus as claimed in Claim 1, further comprising pressure means and control means, said pressure means adapted to measure evacuation of said tube, and provide a signal corresponding to said measurement to said

control means, the control means being adapted to stop evacuation of said tube when said required vacuum is detected.

13. An apparatus as claimed in Claim 12, wherein said control means further includes valve means for stopping evacuation of said tube.

14. An apparatus as claimed in Claim 1, further comprising pressure means for stopping said evacuation means when the required vacuum is in the tube.

15. An apparatus as claimed in Claim 14, wherein said pressure means comprises a pressure sensitive switch.

16. An apparatus as claimed in Claim 14, further comprising a tube sensor for starting said evacuation means.

17. An apparatus as claimed in Claim 1, wherein said evacuation means is time controlled by being intermittently actuated in order to provide said required vacuum.

18. An apparatus as claimed in Claim 1, wherein said evacuation means is speed controlled such that said required vacuum is applied to said tube.

19. A system for collecting a fluid sample comprising :

a tube adapted to receive and retain for a predetermined amount of time, a vacuum, the tube being pierceable so as to provide fluid communication between a fluid reservoir and the interior of said tube and for evacuating the tube, such that the sample drawn is of a predetermined volume in relation to the volume of the tube, just prior to collection of said sample,

said tube being adapted to substantially reseal after piercing so as to hold said vacuum for said time or to hold said sample,

evacuation means mounted in or on a housing and being adapted to evacuate the tube to a required vacuum being derived from a predetermined degree of vacuum or to one of a series of predetermined degrees of vacuum, and

communication means adapted to connect said evacuation means to said tube to enable evacuation of said tube to the required vacuum.

20. A system as claimed in Claim 19, further comprising :

manifold means coupled between said evacuation means and said communication means, and being adapted to selectively determine each predetermined degree of vacuum.

21. A sytem as claimed in Claim 20, wherein said manifold means comprises a selector means having a first portion from which the required vacuum is delivered and a second portion connected to said evacuation means, the second portion having at least one orifice of at least one size, each orifice corresponding to each predetermined degree of vacuum, and further wherein said selector means is adapted to select an orifice such that the corresponding predetermined degree of vacuum is reduced to the required vacuum.

22. A system as claimed in Claim 20, further comprising calibration means coupled to said evacuation means for determining a base line vacuum.

23. A system as claimed in Claim 22, wherein each predetermined degree of vacuum is determined from said base line vacuum.

24. A system as claimed in Claim 22, wherein said calibration means comprises an adjustable vent, being adapted to adjustably reduce vacuum from said evacuation means.

25. A system as claimed in Claim 19, further comprising guage means for providing an indication of vacuum.

26. A system as claimed in Claim 19, wherein said communication means comprises needle means for piercing the tube and enable evacuation of the tube.

27. A system as claimed in Claim 19, further comprising tube sensor means to detect the presence of a suitable tube for evacuation.

28. A system as claimed in Claim 26, wherein said communication means further comprises injector means for moving said needle into communication with said tube for evacuation and to a rest position.

29. A system as claimed in Claim 27, wherein said injector means comprises a motor adapted for one-shot operation and being coupled to an arm mount on an offset cam, the arm being coupled to the needle means, said injector means, upon actuation, moving said needle into a pierposition and into communication with said tube for evacuation and returning to the rest position.

30. A system as claimed in Claim 19, further comprising pressure means and control means, said pressure means adapted to measure evacuation of said tube, and provide a signal corresponding to said measurement to said control means, the control means being adapted to stop evacuation of said tube when said required vacuum is detected.

31. A system as claimed in Claim 30, wherein said control means further includes valve means for stopping evacuation of said tube.

32. A system as claimed in Claim 19, further comprising pressure means for stopping said evacuation means when the required vacuum is in the tube.

33. A system as claimed in Claim 32, wherein said pressure means comprises a pressure sensitive switch.

34. A system as claimed in Claim 32, further comprising a tube sensor for starting said evacuation means.

35. A system as claimed in Claim 19, wherein said evacuation means is time controlled by being intermittently actuated in order to provide said required vacuum.

36. A system as claimed in Claim 19, wherein said evacuation means is speed controlled such that said required vacuum is applied to said tube.

37. A method of sampling a predetermined volume of fluid comprising the steps of :

providing a fluid path means in communication with a fluid reservoir,

selecting the predetermined volume of fluid required to be sampled from the reservoir,

selecting a resealable tube having an enclosed space adapted for evacuation and retaining a prescribed vacuum for a predetermined amount of time,

providing the tube with the vacuum by allowing the tube to be pierced such that communication is provided between a source of vacuum and the interior of the tube until the prescribed vacuum is instilled in the tube, and then disconnecting the tube from the vacuum source, whereby the tube reseals in order to retain the prescribed vacuum,

mating the tube with the fluid path means, piercing the evacuated tube and allowing the predetermined volume of fluid into the tube.

38. A method of providing a resealable tube with a predetermined vacuum, including the steps of :

providing the resealable tube having an enclosed space adapted for evacuation and retaining a prescribed vacuum for a predetermined amount of time,

mating the tube with communication means adapted to connect an evacuation means to said tube to enable evacuation of the tube to the vacuum, the evacuation means being mounted in or on a housing and being adapted to evacuate the tube to the vacume,

allowing the tube to be evacuated by said evacuation means,

withdrawing the tube from the communication means whereby the tube reseals so as to hold the vacuum for the predetermined amount of time.

39. A method of inter-tube transfer of fluid, including the steps of :

providing a tube having the fluid therein,

connecting the fluid tube to a transfer means having a first portion adapted to receive said fluid tube and a second portion adapted to receive an evacuated tube, the first and second portions being fluid connected via a communication means providing a fluid path, the communication means being adapted to connect the interior of the fluid tube and the interior of the evacuated tube for said transfer of fluid,

providing said evacuated tube as described above,

ensuring the communication means is in contact with said fluid,

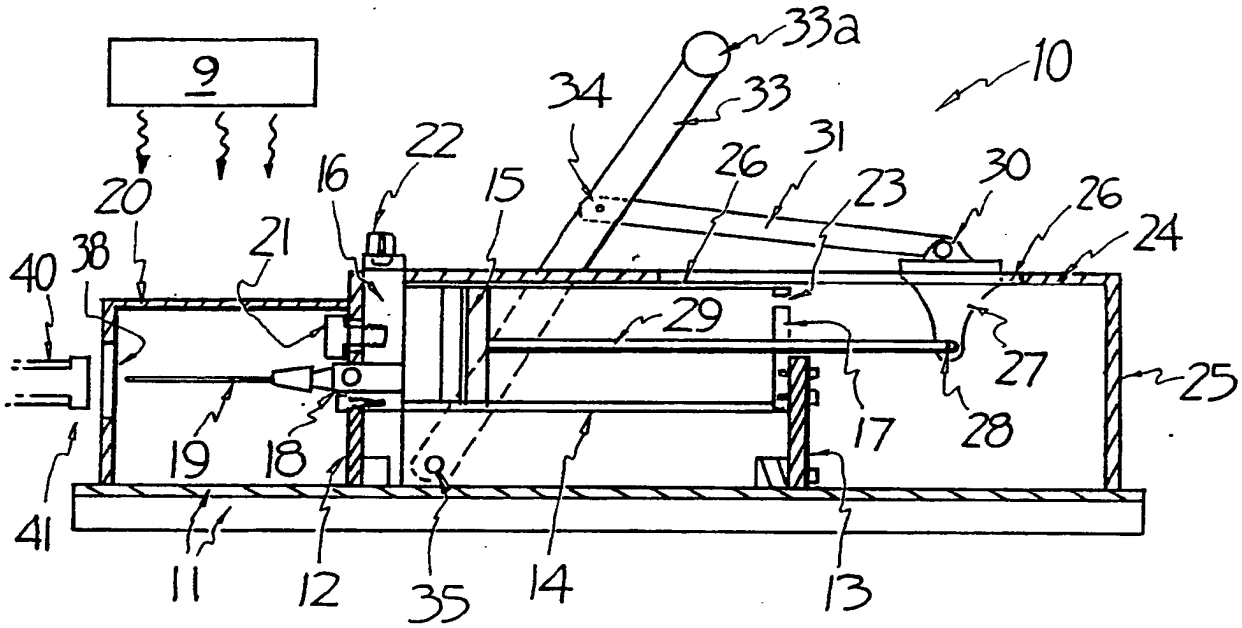
mating the evacuated tube with the communication means so that a fluid is transferred by means of vacuum.

40. An apparatus as claimed in Claim 1, substantially as herein described with reference to the accompanying drawings.

41. A system as claimed in Claim 19, substantially as herein described with reference to the accompanying drawings.

RCTS:JC (6.8)

FIGURE.1



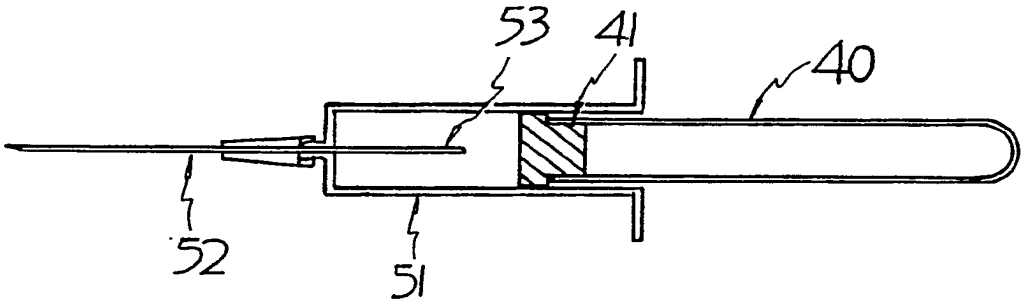


FIGURE.7

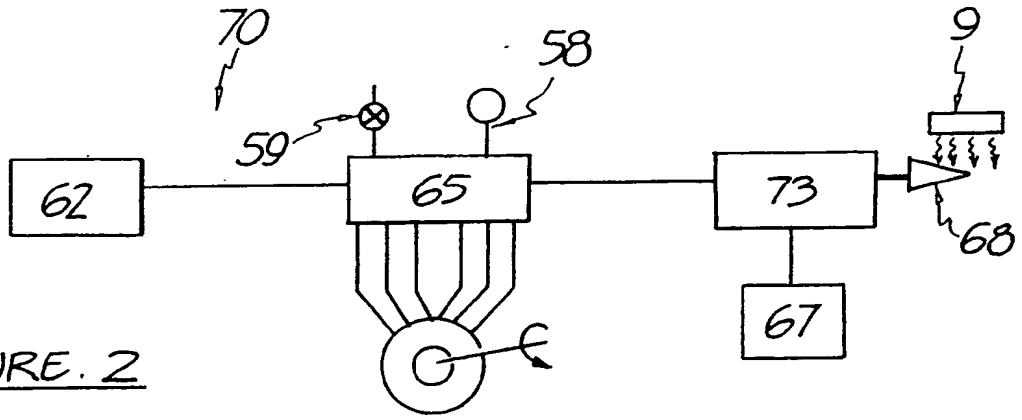


FIGURE. 2

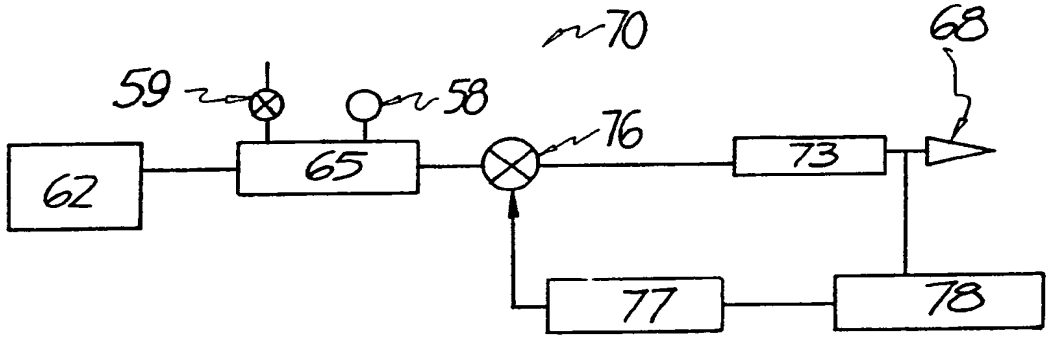


FIGURE. 3

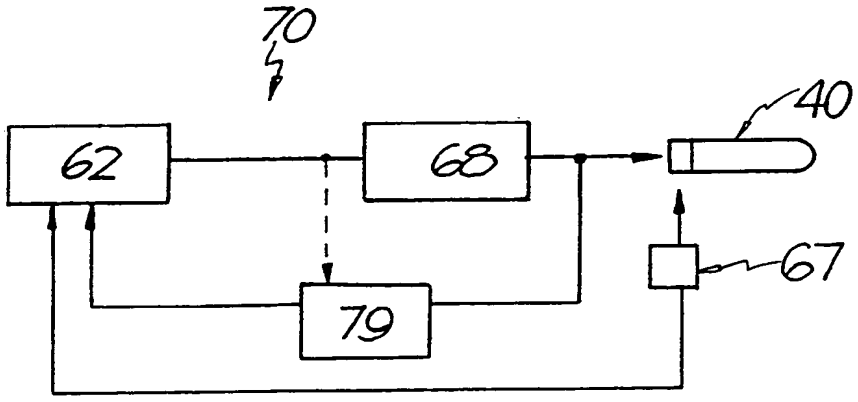
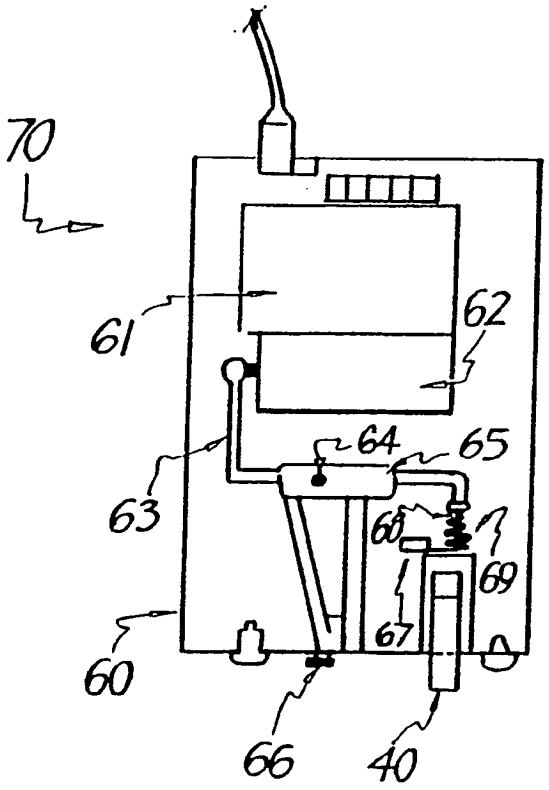
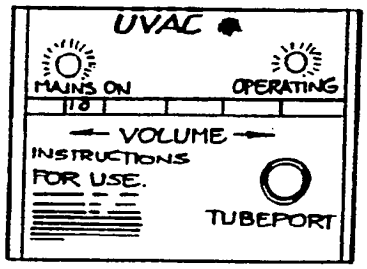


FIGURE. 4

FIGURE. 5

"PLAN VIEW"

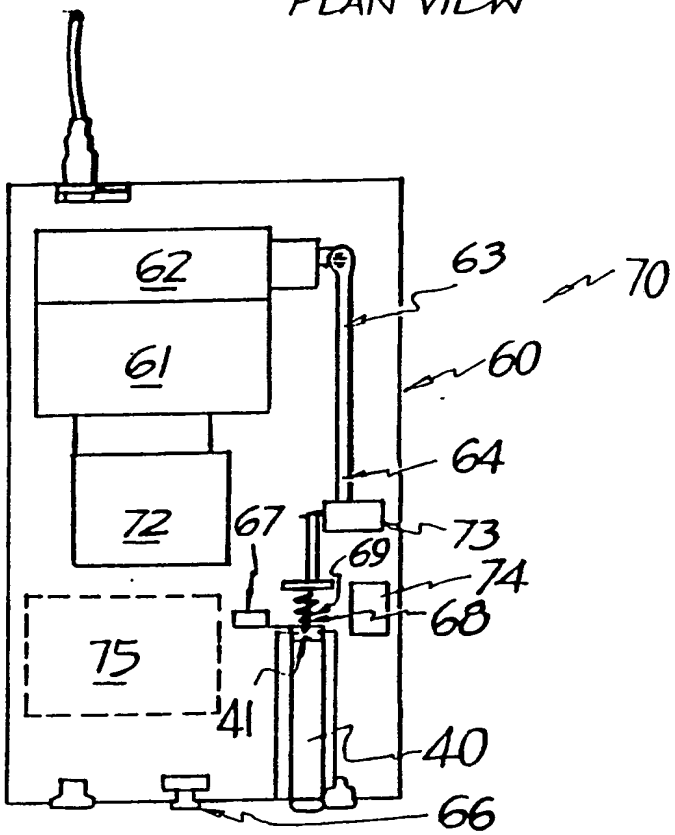


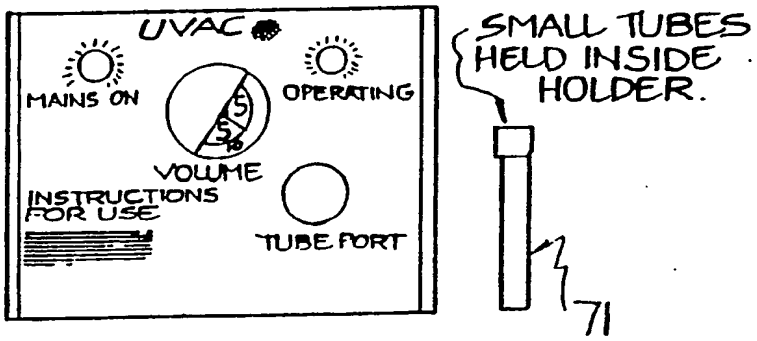


"FRONT PANEL VIEW"

FIGURE.6

"PLAN VIEW"





"FRONT PANEL VIEW."

INTERNATIONAL SEARCH REPORT

International Application No PCT/AU88/00081

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[4] A61B 5/14, A61M 1/02

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC	A61B 5/14, A61M 1/02

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

AU : IPC as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X,Y	GB,A, 1564009 (SVENSSON) 2 April 1980 (02.04.80)	1-10,13-28 32-39
X,Y	US,A, 3433216 (MATTSON) 18 March 1969 (18.03.69)	1-10,12-28, 32-39
X,Y	US,A, 3776218 (SVENSSON) 4 December 1973 (04.12.73)	1-10,13-18
A	US,A, 3633566 (GRAB HORN) 11 January 1972 (11.01.72)	
A	US,A, 4317456 (PERCARPIO) 2March 1982 (02.03.82)	
A	US,A, 4192320 (MEGAHED) 11 March 1980 (11.03.80)	

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
17 JUNE 1988 (17.06.88)	(27.06.88) 27 JUNE 1988
International Searching Authority	**Signature of Authorized Officer**
AUSTRALIAN PATENT OFFICE	R.A. MURRAY

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 88/00081

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Patent Document Cited in Search Report	Patent Family Members		
GB 1564009	AU 17271/76	BE 845570	CA 1098000
	CH 601786	DK 3895/76	FR 2322371
	IT 1065821	LU 75676	NL 7609551
	NO 762963	SE 7609447	US 4063460
	US 4134300		
US 3633566	BE 750378	CA 926718	DE 2022116
	FR 2047706	GB 1313331	NL 7007075
	US 3765402		
US 4317456	AR 223912	AU 67328/81	BE 887842
	BR 8100157	DE 3103031	ES 498753
	ES 8203596	FR 2477403	GB 2071282
	IT 1135503	JP 56143144	LU 83209
	MX 151988	NL 8101063	SE 8100721
	SE 8201739	BR 8207120	DE 3245804
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